



GA
#5/a
4-9
ATTORNEY'S DOCKET NO: C1039/7044 (AWS)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hartmann et al.
Serial No: 09/672,126
Filed: 27 September 2000
For: METHODS RELATED TO IMMUNOSTIMULATORY NUCLEIC
ACID-INDUCED INTERFERON

RECEIVED

JAN 18 2001

TECH CENTER 1600/2900

Examiner: unassigned
Art Unit: 1646

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the 10th day of January, 2001.

Monica E. Zombori

Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ Form PTO-1449 and References Cited
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No check is enclosed. If a fee is determined to be required, the balance may be charged to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Hartmann et al., Applicant(s)

By:

Alan W. Steele, Reg. No. 45,128
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210
Telephone (617) 720-3500

Docket No. C1039/7044 (AWS)
Dated: January 10, 2001

09/672126



ATTORNEY'S DOCKET NO: C1039/7044 (AWS)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

Applicant: Hartmann et al.

Serial No: 09/672,126

Filed: 27 September 2000

For: METHODS RELATED TO IMMUNOSTIMULATORY NUCLEIC
ACID-INDUCED INTERFERON

JAN 18 2001

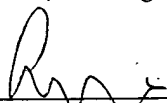
TECH CENTER 1600/2900

Examiner: unassigned

Art Unit: 1646

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the 10th day of January, 2001.


Alan W. Steele, Reg. No. : 45,128

Commissioner for Patents
Washington, D.C. 20231

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

PART III: Remarks

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Hartmann et al., Applicant(s)

By: 

Alan W. Steele, Reg. No. 45,128
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210
Telephone (617) 720-3500

Docket No. C1039/7044 (AWS)
Dated: January 10, 2001

FORM PTO-1449(Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
	APPLICANT Hartmann et al.	
	FILING DATE September 27, 2000	GROUP 1646

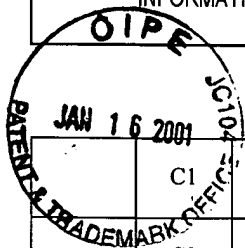
U.S. PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	A1	3,906,092	09/16/75	Hilleman et al.	424	89	
	A2	4,469,863	09/04/84	Ts'o et al.	536	24.5	
	A3	5,023,243	06/11/91	Tullis	514	44	RECEIVED
	A4	5,248,670	09/28/93	Draper et al.	514	454	
	A5	5,359,052	10/25/94	Stee et al.	536	26.7	JAN 18 2001
	A6	5,512,668	04/30/96	Stec et al.	536	25.33	
	A7	5,585,479	12/17/96	Hoke et al.	536	24.5	TECH CENTER 1600/2000
	A8	5,635,363	06/03/97	Altman et al.	435	7.24	
	A9	5,663,153	09/02/97	Hutcherson et al.	514	44	
	A10	5,723,335	03/03/98	Hutcherson et al.	435	375	
	A11	5,786,189	07/28/98	Locht et al.	424	200.1	
	A12	5,849,719	12/15/98	Carson et al.	514	44	
	A13	5,856,465	01/05/99	Stec et al.	536	25.3	
	A14	5,883,237	03/16/99	Stec et al.	536	23.1	

FOREIGN PATENT DOCUMENTS

		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No	
	B1	EP 0302758 B1	02/08/89	EPO	C12N	15/37		
	B2	EP 0174143 B1	11/08/89	EPO	C07K	15/26		
	B3	WO 91/12811	09/05/91	WIPO	A61K	31/70		
	B4	EP 0468520 A2	01/29/92	EPO	A61K	31/70		
	B5	WO 92/03456	04/05/92	WIPO	C07H	15/12		
	B6	EP 0092574 B1	04/29/92	EPO	C07H	21/02		
	B7	WO 92/18522	10/29/92	WIPO	C07H	21/00		
	B8	WO 92/21353	12/10/92	WIPO	A61K	31/70		
	B9	WO 94/19945	09/15/94	WIPO	A01N	43/04		
	B10	WO 95/05853	03/02/95	WIPO	A61K	48/00		
	B11	WO 95/26204	10/05/95	WIPO	A61K	48/00		
	B12	WO 96/02555	02/01/96	WIPO	C07H	21/00		
	B13	WO 96/35782	11/14/96	WIPO	C12N	15/11		
	B14	WO 97/28259	08/07/97	WIPO	C12N	15/00		
	B15	WO 98/14210	04/09/98	WIPO	A61K	39/35		
	B16	WO 98/18810	05/07/98	WIPO	C07H	21/00		
	B17	WO 98/37919	09/03/98	WIPO	A61K	49/00		
	B18	WO 98/40100	09/17/98	WIPO	A61K	39/39		
	B19	WO 98/52581	11/26/98	WIPO	A61K	35/00		

FORM PTO-1449(Modified)	ATTY. DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
	LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	
	APPLICANT Hartmann et al.	
	FILING DATE September 27, 2000	GROUP 1646

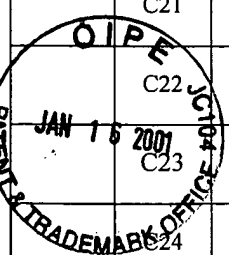


OTHER ART

(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

C1	Altman JD et al. Phenotypic analysis of antigen-specific T lymphocytes. <i>Science</i> 1996 Oct 4;274(5284):94-6.
C2	Ballas ZK et al. Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 1996 Sep 1;157(5):1840-5.
C3	Banchereau J and Steinman RM. Dendritic cells and the control of immunity. <i>Nature</i> 1998 Mar 19;392(6673):245-52.
C4	Beaucage SL and Caruthers MH. Deoxynucleoside phosphoramidites - a new class of key intermediates for deoxypolynucleotide synthesis. <i>Tetrahedron Lett</i> 1981;22(20):1859-62.
C5	Cascinu S et al. A phase I trial of 5-fluorouracil, leucovorin and interferon-alpha 2b administered by 24 h infusion in metastatic colorectal carcinoma. <i>Anticancer Drugs</i> 1996 Jul;7(5):520-4.
C6	Cella M et al. Plasmacytoid monocytes migrate to inflamed lymph nodes and produce large amounts of type I interferon. <i>Nat Med</i> 1999 Aug;5(8):919-23.
C7	Chace JH et al. Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. <i>Clin Immunol Immunopathol</i> 1997 Aug;84(2):185-93.
C8	Chehimi J et al. Dendritic cells and IFN-alpha-producing cells are two functionally distinct non-B, non-monocytic HLA-DR+ cell subsets in human peripheral blood. <i>Immunology</i> 1989 Dec;68(4):488-90.
C9	Cowdery JS et al. Bacterial DNA induces NK cells to produce IFN-gamma in vivo and increases the toxicity of lipopolysaccharides. <i>J Immunol</i> 1996 Jun 15;156(12):4570-5.
C10	Froehler BC et al. Synthesis of DNA via deoxynucleoside H-phosphonate intermediates. <i>Nucleic Acids Res</i> 1986 Jul 11;14(13):5399-407.
C11	Gaffney et al. Large-scale oligonucleotide synthesis by the H-phosphonate method. <i>Tetrahedron Lett</i> 1988;29(22):2619-22.
C12	Galy A et al. Distinct signals control the hematopoiesis of lymphoid-related dendritic cells. <i>Blood</i> 2000 Jan 1;95(1):128-37.
C13	Garegg et al. Nucleoside H-phosphonates. III. Chemical synthesis of oligodeoxyribonucleotides by the hydrogenphosphonate approach. <i>Tetrahedron Lett</i> 1986;27(34):4051-4.
C14	Garegg et al. Nucleoside H-phosphonates. IV. Automated solid phase synthesis of oligoribonucleotides by the hydrogenphosphonate approach. <i>Tetrahedron Lett</i> 1986;27(34):4055-8.
C15	Gill PS et al. Interferon-alpha maintenance therapy after cytotoxic chemotherapy for treatment of acquired immunodeficiency syndrome-related Kaposi's sarcoma. <i>J Biol Response Mod</i> 1990 Oct;9(5):512-6.
C16	Goeddel DV et al. The structure of eight distinct cloned human leukocyte interferon cDNAs. <i>Nature</i> 1981 Mar 5;290(5801):20-6.
C17	Goodchild J. Conjugates of oligonucleotides and modified oligonucleotides: a review of their synthesis and properties. <i>Bioconjugate Chem</i> 1990 May/June;1(3):165-87.
C18	Gray PW et al. Expression of human immune interferon cDNA in E. coli and monkey cells. <i>Nature</i> 1982 Feb 11;295(5849):503-8.
C19	Grouard G et al. The enigmatic plasmacytoid T cells develop into dendritic cells with interleukin (IL)-3 and CD40-ligand. <i>J Exp Med</i> 1997 Mar 17;185(6):1101-11.
C20	Halpern MD et al. Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. <i>Cell Immunol</i> 1996 Jan 10;167(1):72-8.

FORM PTO-1449(Modifi d) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
	APPLICANT Hartmann et al.	
	FILING DATE September 27, 2000	GROUP 1646

	C21	Halpern MD et al. In vitro inhibition of murine IFN gamma production by phosphorothioate deoxyguanosine oligomers. <i>Immunopharmacology</i> 1995 Feb;29(1):47-52.
	C22	Hartmann G et al. CpG DNA and LPS induce distinct patterns of activation in human monocytes. <i>Gene Ther</i> 1999 May;6(5):893-903.
	C23	Hartmann G et al. CpG DNA: a potent signal for growth, activation, and maturation of human dendritic cells. <i>Proc Natl Acad Sci USA</i> 1999 Aug 3;96(16):9305-10.
	C24	Hartmann G et al. Delineation of a CpG phosphorothioate oligodeoxynucleotide for activating primate immune responses in vitro and in vivo. <i>J Immunol</i> 2000 Feb 1;164(3):1617-24.
	C25	Hartmann G et al. Mechanism and function of a newly identified CpG DNA motif in human primary B cells. <i>J Immunol</i> 2000 Jan 15;164(2):944-53.
	C26	Hartmann G et al. Specific suppression of human tumor necrosis factor-alpha synthesis by antisense oligodeoxynucleotides. <i>Antisense Nucleic Acid Drug Dev</i> 1996 Winter;6(4):291-9.
	C27	Hartmann G et al. Spontaneous and cationic lipid-mediated uptake of antisense oligonucleotides in human monocytes and lymphocytes. <i>J Pharmacol Exp Ther</i> 1998 May;285(2):920-8.
	C28	Iho S et al. Oligodeoxynucleotides containing palindrome sequences with internal 5'-CpG-3' act directly on human NK and activated T cells to induce IFN-gamma production in vitro. <i>J Immunol</i> 1999 Oct 1;163(7):3642-52.
	C29	Kimura Y et al. Binding of oligoguanylate to scavenger receptors is required for oligonucleotides to augment NK cell activity and induce IFN. <i>J Biochem (Tokyo)</i> 1994 Nov;116(5):991-4.
	C30	Klinman DM et al. CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. <i>Proc Natl Acad Sci USA</i> 1996 Apr 2;93(7):2879-83.
	C31	Kranzer K et al. CpG-oligodeoxynucleotides enhance T-cell receptor-triggered interferon-gamma production and up-regulation of CD69 via induction of antigen-presenting cell-derived interferon type I and interleukin-12. <i>Immunology</i> 2000 Feb;99(2):170-8.
	C32	Krieg AM et al. CpG motifs in bacterial DNA trigger direct B-cell activation. <i>Nature</i> 1995 Apr 6;374(6522):546-9.
	C33	Krieger M and Herz J. Structures and functions of multiligand lipoprotein receptors: macrophage scavenger receptors and LDL receptor-related protein (LRP). <i>Annu Rev Biochem</i> 1994;63:601-37.
	C34	Kuzel TM et al. Interferon alfa-2a combined with phototherapy in the treatment of cutaneous T-cell lymphoma. <i>J Natl Cancer Inst</i> 1990 Feb 7;82(3):203-7.
	C35	Lipford GB et al. Poly-guanosine motifs costimulate antigen-reactive CD8 T cells while bacterial CpG-DNA affect T-cell activation via antigen-presenting cell-derived cytokines. <i>Immunology</i> 2000 Sep;101(1):46-52.
	C36	Lyons AB and Parish CR. Determination of lymphocyte division by flow cytometry. <i>J Immunol Methods</i> 1994 May 2;171(1):131-7.
	C37	Macaya RF et al. Thrombin-binding DNA aptamer forms a unimolecular quadruplex structure in solution. <i>Proc Natl Acad Sci USA</i> 1993 Apr 15;90(8):3745-9.
	C38	O'Doherty U et al. Dendritic cells freshly isolated from human blood express CD4 and mature into typical immunostimulatory dendritic cells after culture in monocyte-conditioned medium. <i>J Exp Med</i> 1993 Sep 1;178(3):1067-76.
	C39	Perera F et al. A phase I pilot study of pelvic radiation and alpha-2A interferon in patients with locally advanced or recurrent rectal cancer. <i>Int J Radiat Oncol Biol Phys</i> 1997 Jan 15;37(2):297-303.
	C40	Pisetsky DS et al. Stimulation of in vitro proliferation of murine lymphocytes by synthetic oligodeoxynucleotides. <i>Mol Biol Rep</i> 1993 Oct;18(3):217-21.

FORM PTO-1449(Modified)	ATTY: DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
	APPLICANT Hartmann et al.	
	FILING DATE September 27, 2000	GROUP 1646

C41	Pulendran B et al. Distinct dendritic cell subsets differentially regulate the class of immune response in vivo. <i>Proc Natl Acad Sci USA</i> 1999 Feb 2;96(3):1036-41.
C42	Qiu B and Chen M. Treatment of cutaneous T cell lymphoma with low doses of interferon alpha-2b. <i>Chin Med J (Engl)</i> 1996 May;109(5):404-6.
C43	Ramanathan M et al. Inhibition of interferon-gamma-induced major histocompatibility complex class I expression by certain oligodeoxynucleotides. <i>Transplantation</i> 1994 Feb 27;57(4):612-5.
	Rissoan M-C et al. Reciprocal control of T helper cell and dendritic cell differentiation. <i>Science</i> 1999 Feb 19;283(5405):1183-6.
C45	Sato Y et al. Immunostimulatory DNA sequences necessary for effective intradermal gene immunization. <i>Science</i> 1996 Jul 19; 273(5273):352-4.
C46	Siegal F et al. The nature of the principal type 1 interferon-producing cells in human blood. <i>Science</i> 1999 Jun 11;284(5421):1835-7.
C47	Stec WJ et al. Diastereomers of nucleoside 3'-O-(2-thio-1,3,2-oxathia(selena)phospholanes): building blocks for stereocontrolled synthesis of oligo(nucleoside phosphorothioate)s. <i>J Am Chem Soc</i> 1995;17:12019.
C48	Sun S et al. Multiple effects of immunostimulatory DNA on T cells and the role of type I interferons. <i>Springer Semin Immunopathol</i> 2000;22(1-2):77-84.
C49	Sun S et al. Type I interferon-mediated stimulation of T cells by CpG DNA. <i>J Exp Med</i> 1998 Dec 21;188(12):2335-42.
C50	Tanaka Y et al. Natural and synthetic non-peptide antigens recognized by human gamma delta T cells. <i>Nature</i> 1995 May 11;375(6527):155-8.
C51	Thomas R and Lipsky PE. Human peripheral blood dendritic cell subsets. Isolation and characterization of precursor and mature antigen-presenting cells. <i>J Immunol</i> 1994 Nov 1;153(9):4016-28.
C52	Tokunaga T et al. Antitumor activity of deoxyribonucleic acid fraction from Mycobacterium bovis BCG. I. Isolation, physicochemical characterization, and antitumor activity. <i>J Natl Cancer Inst</i> 1984 Apr;72(4):955-62.
C53	Tokunaga T et al. A synthetic single-stranded DNA, poly(dG,dC), induces interferon-alpha/beta and -gamma, augments natural killer activity, and suppresses tumor growth. <i>Jpn J Cancer Res</i> 1988 Jun;79(6):682-6.
C54	Tokunaga T et al. Synthetic oligonucleotides with particular base sequences from the cDNA encoding proteins of Mycobacterium bovis BCG induce interferons and activate natural killer cells. <i>Microbiol Immunol</i> 1992;36(1):55-66.
C55	Trinchieri G. Biology of natural killer cells. <i>Adv Immunol</i> 1989;47:187-376.
C56	Uhlmann E and Peyman A. Antisense oligonucleotides: a new therapeutic principle. <i>Chem Rev</i> 1990 Jun;90(4):544-84.
C57	Vallin H et al. Anti-double-stranded DNA antibodies and immunostimulatory plasmid DNA in combination mimic the endogenous IFN-alpha inducer in systemic lupus erythematosus. <i>J Immunol</i> 1999 Dec 1;163(11):6306-13.
C58	Wagner RW et al. Potent and selective inhibition of gene expression by an antisense heptanucleotide. <i>Nat Biotechnol</i> 1996 Jul;14(7):840-4.
C59	Wyatt JR et al. Combinatorially selected guanosine-quartet structure is a potent inhibitor of human immunodeficiency virus envelope-mediated cell fusion. <i>Proc Natl Acad Sci USA</i> 1994 Feb 15;91(4):1356-60.
C60	Yamamoto S et al. DNA from bacteria, but not from vertebrates, induces interferons, activates natural killer cells and inhibits tumor growth. <i>Microbiol Immunol</i> 1992;36(9):983-97.

FORM PTO-1449(Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
	APPLICANT Hartmann et al.	
	FILING DATE September 27, 2000	GROUP 1646

	C61	Yamamoto S et al. In vitro augmentation of natural killer cell activity and production of interferon-alpha/beta and -gamma with deoxyribonucleic acid fraction from Mycobacterium bovis BCG. <i>Jpn J Cancer Res</i> 1988 Jul;79(7):866-73.
	C62	Yamamoto S et al. Unique palindromic sequences in synthetic oligonucleotides are required to induce IFN and augment IFN-mediated natural killer activity. <i>J Immunol</i> 1992 Jun 15;148(12):4072-6.
	C63	Yamamoto T et al. Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length. <i>Antisense Res Dev</i> 1994 Summer;4(2):119-22.
	C64	Yi AK et al. Rapid immune activation by CpG motifs in bacterial DNA. Systemic induction of IL-6 transcription through an antioxidant-sensitive pathway. <i>J Immunol</i> 1996 Dec 15;157(12):5394-402.
	C65	Zhong RK et al. Human blood dendritic cell-like B cells isolated by the 5G9 monoclonal antibody reactive with a novel 220-kDa antigen. <i>J Immunol</i> 1999 Aug 1;163(3):1354-62.

* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

EXAMINER	DATE CONSIDERED
----------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to applicant

